REMARKS

These remarks are being filed in response to the Office Action mailed December 6, 2007 (the "Office Action") and as a supplement to Amendment B filed February 12, 2008. At the time of the Office Action, claims 1-16 and 20 were pending. The Office Action rejected all of the claims under 35 U.S.C. §103. By this Amendment, claim 26 is added and claim 5 amended. No new matter is added. The rejections and response thereto are set forth fully below.

Amendments to the Claims

By this Amendment, claim 26 is added and claim 5 is amended. New claim 26 recites, "The bone replacement material according to Claim 1, wherein x ranges between 0.1 and 1." Support for claim 26 can be found throughout the specification, including paragraph [0006].

By this Amendment, claim 5 is amended to depend on claim 2, rather than claim 1. Applicants note that antecedent basis for the reference to SiO_2 in claim 5 can be found in the following passage from claim 2: "mixing raw materials containing (in % by weight) 34-48 CaO, 1.5-10.5 Na_2O, 1-11 K_2O, 1.5-3 MgO and 0.1-4 SiO_2."

A claim parallel to claim 5 was rejected under 35 U.S.C. §112, first paragraph, in an Office Action in related case 10/689,219, entitled "Bone Replacement Material Comprising Crystalline and X-Ray Amorphous Phases." During an interview with Examiner Azpuru relating to the '217 Application, it was determined that amending to claim 5 to depend on claim 2, would overcome a rejection under 35 U.S.C. § 112, first paragraph. A parallel amendment for the '219 case was filed concurrently with this Amendment. Both amendments are believed to place the applications in condition for allowance.

Claims Rejections – 35 USC § 103

Claims 1-16 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO91/07357 issued to Berger *et al.* (hereinafter "Berger").

The position of the Examiner can be found on pages 2-3 of the Office Action. Applicants

note that the Office Action refers exclusively to the English language abstract of the German-language Berger disclosure and claim 8 (although the Office Action refers to claim 7, it appears claim 8 was intended). The Examiner states that:

> [Berger] sets out the same raw materials as claimed herein. Berger forms a crystalline and amorphous phase. Processing of the material appears to utilize heat melting of the materials. It is therefore the position of this examiner, that those of ordinary skill would have expected not only the same composition characteristics from the work up of these materials as taught by Berger et al, but also the same bone replacement effects.

Office Action page 2-3.

In the previous response Applicants submitted arguments that the specific starting composition and process steps set forth in claim 2 are required to produce the claimed bone replacement materials. In addition, because Berger discloses different starting materials and different thermal processing, the Berger Patent produces a distinctly different product with different properties. In response, the Office Action indicates that in order to distinguish between the claimed composition and the Berger compositions, "applicant[s] would be required to show that the same materials produce different NMR, X-Ray diffractometric measurements and the X-ray amorphous and crystal phases [of Berger] differ from what is currently claimed." In response, Applicants submit the accompanying Declaration Under 37 C.F.R. §1.132 By Dr. G.M. Berger (hereinafter "Berger Declaration"), which is discussed in more detail below.

In order to render the claimed invention obvious, the reference must disclose or suggest both the desirability of the claimed composition and a method of creating the claimed composition. Applicants are well acquainted with WO 91/07357, as it concerns another invention by Dr. Berger. Based on the following discussion, it should become clear that Berger simply does not meet this standard, because Berger does not disclose or suggest either the necessary starting materials or the thermal treatment required to form the resulting crystalline and amorphous phases and inorganic compounds of the claimed invention.

In order to render the claimed invention obvious, the reference must disclose or suggest the claimed bone replacement material. As noted in the Berger Declaration, declarant Berger is

the first named inventor of the Berger patent and the instant application. During Dr. Berger's research he has had the opportunity to characterize the properties, including the crystalline and amourphous phase content and inorganic chemical composition, of both the claimed bone replacement material and the materials disclosed in the Berger patent. Dr. Berger is a highly distinguished chemist whose career in biomaterials spans more than 32 years and includes approximately 160 publications.

Based on the following discussion and the data provided in the Berger Declaration, it should be clear that the Berger reference simply does not disclose or suggest the claimed bone replacement materials. This is because the Berger reference does not disclose or suggest either the necessary starting materials or the thermal treatment required to form the claimed bone replacement materials, which include claimed crystal and amorphous phases and specific inorganic compounds in specified amounts. The Berger Declaration distinguishes the crystalline and amorphous phases and inorganic compounds, including diphosphates, using the same ^{31}P-NMR measurements and X-ray diffractometric measurements used to define the pending claims, *see* Berger Declaration, section 3. In addition, the Berger Declaration demonstrates that these differences in crystalline and amorphous phases and the inorganic compounds present result in substantially different solubility rates, *see* Berger Declaration, section 3.

As set forth in section 3 of the Berger Declaration:

> It is well known in the art that the type of *crystalline phases and amorphous phases* and the relative amounts of each are directly linked to the starting materials and the melting and cooling process to which the starting materials are exposed. A factor of significant importance to the resulting crystalline and amorphous phases is the particular tempering steps to which the starting material is exposed.
>
> Similarly, it is well known that the *specific inorganic compounds* formed during a heating and cooling process are directly linked to the hold points and maximum temperature reached during the thermal process. Instant claim 2 is a product-by-process claim reciting specific conditions and starting materials for preparing the claimed powder mixture, which recites both specific inorganic compounds and specific crystalline and amorphous phases. ***The conditions and starting materials set forth in claim 2 are the only***

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method I am aware of for producing the mixture of crystalline and amorphous phases with the claimed mixture of orthophosphates, diphosphates, and, as in claim 3, chain phosphates.

Berger Declaration, section 3.

As requested in the Office Action, the Berger Declaration provides a comparison of the claimed bone replacement materials and the Berger materials based on X-Ray diffractometry, ^{31}P-NMR measurements, and other properties of the end product. It is noteworthy that these comparisons are made using the same techniques used to define the pending claims. The comparison provided by the Berger Declaration is reproduced below as Comparison Table 1.

Process	
U.S. Serial No. 10/689,217	**Berger (WO 91/07357)**
1. Melting together a powder mixture of CaO 34-48% P_2O_5 44-54% Na_2O 1.5-10.5% K_2O 1-11% MgO 1.5-3% SiO_2 0.1-4%	1. Melting together a powder mixture of CaO 20-55% P_2O_5 30-50% Na_2O 5-25% K_2O 0-15% MgO 0-15% SiO_2 0-15% 0-40 wt-% Na_2SO_4 and/or K_2SO_4
2. Step-by-step heating with holds for tempering at: a) 350-450°C b) 750-850°C c) 950-1050°C	2. No tempering holds at heating
3. Melting temperature 1550-1650°C	3. Melting temperature 1200-1580°C
4. Spontaneous cooling or temperature-controlled cooling	4. Spontaneous cooling or temperature-controlled cooling
5. No holding steps during cooling	5. Optional holding step at 600-1200°C during the cooling
6. **PRODUCT:** A powder mixture of crystal phases $Ca_{10}Na(PO_4)_7$, $Ca_{10}K(PO_4)_7$, $Ca_{10}K_XNa_{1-X}(PO_4)_7$, $Na_2CaP_2O_7$, $K_2CaP_2O_7$, $Ca_2P_2O_7$ and X-ray amorphous (non-crystal) phases.	6. **PRODUCT:** A glassy or glassy-crystal body with the phases rhenanite = $CaNaPO_4$ phase X = $Ca_2KNa(PO_4)_2$ phase A = $Ca_5Na_2(PO_4)_4$ glaserite = $K_3Na(SO_4)_2$

Process	
U.S. Serial No. 10/689,217	**Berger (WO 91/07357)**
	crystalline potassium sulfate = K_2SO_4 and their mixed crystals.
7. **PRODUCT**: 0.1-35 wt-% diphosphates	7. **PRODUCT**: 0% diphosphates
8. **PRODUCT SOLUBILITY**: 60-250µg/mg (claim 13)	8. **PRODUCT SOLUBILITY** 1-15 mg/g

Berger Declaration, section 3.

Dr. Berger provides insight into the differences between the claimed bone replacement materials and the materials disclosed in Berger. In the Berger Declaration, Dr. Berger states:

> The clearly distinguishable crystal phases and compositions in Berger and the claims of the Application result because of their divergent thermal history and the different starting materials. The starting materials in Berger include 0-40 wt-% Na_2SO_4 and/or K_2SO_4, whereas the current Application does not mention Na_2SO_4 or K_2SO_4, much less include either in the claims. The claimed bone replacement material is formed using a much narrower range of starting materials.
>
> This divergent thermal history is clearly set forth for ease of comparison in rows 2 and 3 of Comparison Table 1, below, and the following summary:
>
> - The claimed invention includes three holds (350-450°C, 750-850°C and 950-1,050°C) during the heating process, Berger discloses none.
> - The claimed invention has a maximum heating temperature of 1550-1650°C, whereas Berger's maximum heating temperature is 1200-1580°C.
> - The claimed invention provides for spontaneous cooling or temperature-controlled cooling without any holding step, whereas Berger includes a holding step in the range of 600-1200°C.
>
> Further evidence that the claimed bone replacement material is neither disclosed nor suggested by the Berger materials is demonstrated by the substantially different solubility exhibited by each (1-15mg/g v. 60-250 mg/g).
>
> As set forth in the table above, the process disclosed in Berger

produces A glassy or glassy-crystal material with the following phases: rhenanite = $CaNaPO_4$; phase X = $Ca_2KNa(PO_4)_2$; phase A = $Ca_5Na_2(PO_4)_4$; glaserite = $K_3Na(SO_4)_2$; crystalline potassium sulfate = K_2SO_4; and their mixed crystals. None of these compounds is found in the product of the claimed subject matter, *see* claim 1.(b) & 2.(b). Furthermore, the presence of any of these compounds in the main crystal phase would clearly fall outside of the claims.

Berger Declaration, section 3.

Dr. Berger then addresses the absence of diphosphates in the materials disclosed in the Berger reference. Dr. Berger notes that:

One of the significant differences is the presence of Q_1 groups of diphosphates ($Na_7CaP_2O_7$, $K_2CaP_2O_7$, $Ca_2P_2O_7$) measured by ^{31}P-MAS-NMR measurements.

Enclosed Fig. 1 of a ^{31}P-MAS-NMR spectra shows peaks of orthophosphates in the δ range of +5 to -2. Further it shows peaks of diphosphates in the δ range of -7.5 to -9.5.

The starting materials for the bone replacement materials evaluated in Fig. 1 and Fig. 2 came from the following raw materials:

Fig. 1 (material of application 10/689,217): CaO 39.86 wt-%, MgO 1.25 wt-%, P_2O_5 46.82 wt-%; Na_2O 4.79 wt-%; KiO 7.28 wt-%

Fig. 2 (material of application No. 10/689,219): CaO 29.92 wt-%; MgO 2.39 wt-%, P_7O_5 44.53 wt-%, Na_2O 9.19 wt-%; K_2O 13.97 wt-%

The materials used for Fig. 1 and 2 above were prepared according to the method of the present invention with holding steps during the heating procedure at 400, 800 and 1000°C and a melting temperature of 1600°C.

Fig. 3 is a material according to the Berger reference W091/07357, where the starting materials were melted at a temperature of 1550°C and without any holding steps. The material with the following composition: 32.33 wt-% CaO; 1.22 wt-% MgO; 9.4 wt-% Na_2O; 14.3 wt-% K_2O; 40.93 wt-% P_2O_5; and 1.82 wt-% SiO_2. The materials produced according to Berger show orthophosphate peaks but no diphosphate peaks using ^{31}P-MAS-NMR.

The Berger materials include crystal phases of $CaNaPO_4$. $Ca_2KNa(P04)_2$ and $CasNa_2(PO_4)_4$. The Berger crystal phases are completely different from the Ca_{10} phases of the current application.

Berger Declaration, section 3.

Relying on both the data provided and all of his expertise in the field of biomaterials, Dr. Berger concludes that:

> the Berger reference neither discloses nor suggests the claimed bone replacement material or the process of making the claimed bone replacement material. It is also my opinion that the data supplied herein clearly demonstrates that the vitreous or vitreous crystalline, rapidly dissolving materials disclosed in Berger have different crystalline and amorphous phases and include different inorganic compounds than the claims of the Application. Furthermore, the differences in process and end product between Berger and the claims of the Application are not disclosed or suggested by Berger.

Berger Declaration, section 4.

In the response to arguments section of the Office Action, the Examiner states that in order to distinguish between the claimed bone replacement material and the Berger material, "applicant[s] would be required to show that the same materials produce different NMR, X-Ray diffractometric measurements and the X-ray amorphous and crystal phases [of Berger] differ from what is currently claimed." Applicants respectfully submit that the data and analysis provided by the Berger declaration is more than sufficient to demonstrate that the claimed bone replacement materials comprise substantial differences in crystalline and amorphous phases, inorganic compounds (orthophosphates, diphosphates), and solubility. In conclusion, neither the claimed bone replacement materials, nor the starting materials and thermal histories required to produce the claimed bone replacement materials, are disclosed or suggested by the Berger reference.

Conclusion

For at least the reasons set forth above, the independent claims are believed to be allowable. In addition, the dependent claims are believed to be allowable due to their dependence on an allowable base claim and for further features recited therein. The application is believed to be in condition for immediate allowance. If any issues remain outstanding, Applicant invites the Examiner to call the undersigned, Greg Lefkowitz (direct line 561-671-

3624), if it is believed that a telephone interview would expedite the prosecution of the application to an allowance.

Respectfully submitted,

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